K122573

510(k) Summary

NOV 20 2012

The 510(k) Summary is submitted in accordance with 21 CFR §807.92 and the requirements of the Safe Medical Device Act (SMDA) of 1990.

1. Submitter's Name	Abbott Vascular Inc.
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4. Fax	(951) 914-0339
5. Contact Person	Kay Setzer
6. Date Prepared	August 22, 2012
7. Device Trade Name	Hi-Torque Command Guide Wire Family
8. Device Common Name	Guide Wire
9. Device Classification Name	Catheter Guide Wire (DQX)
10. Predicate Device(s) Name	HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL II Guide Wire (K072460, cleared April 11, 2008); HI-TORQUE BALANCE HEAVYWEIGHT (K021228, cleared May15, 2002), HI-TORQUE BMW ELITE (K103101, cleared Feb. 10, 2011), HI-TORQUE WHISPER, (K101116, cleared June 23, 2010); and HI-TORQUE POWERTURN (K112957, cleared Feb. 8, 2011).

11. Device Description

The Abbott Vascular 0.014" Hi-Torque Command (HT Command) Guide Wire with hydrophilic and hydrophobic coatings is a stainless steel and nitinol steerable guide wire with a maximum diameter of 0.0145", provided in 190 cm extendable, 250 cm, and 300 cm exchange lengths. The distal tip has a radiopaque length of 3.0 cm. The distal tip is straight and shapeable. The HT Command Guide Wire Family consists of two models with differing flexibility and performance; the HT Command and the HT Command ES. The proximal end of the 190 cm model is plunge ground and coined to fit into the hypotube portion of the DOC® Guide Wire Extension. The HT Command guide wire family is compatible with devices designed for use with 0.014" guide wires.

12. Indication for Use

The Hi-Torque Command Guide Wire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal angioplasty (PTA), in arteries such as the femoral, popliteal and infra-popliteal arteries. This guide wire may also be used with compatible stent devices during therapeutic procedures.

The guide wire may also be used to reach and cross a target lesion, provide a pathway within a vessel structure, facilitate the substitution of one diagnostic or interventional device for another, and to distinguish the vasculature.

13. Technological Characteristics

Comparisons of the new and predicate devices show that the technological characteristics such as product performance, design and indications for use are substantially equivalent to the currently marketed predicate devices.

14. Performance Data

In vitro bench testing conducted on the subject device included:

- catheter compatibility,
- radiopacity,
- tensile strength,
- torque strength,
- torque accuracy,
- coating adherence and integrity (particulate testing), and
- friction testing.

The *in vitro* bench tests demonstrated that the Hi-Torque Command Guide Wire met all acceptance criteria and performed similarly to the predicate devices.

15. Leveraged testing

Biocompatibility, packaging, and sterilization testing were not necessary as the Hi-Torque Command is identical in materials, packaging, and sterilization as the predicate devices.

16. Conclusions

Test results from the non-clinical *in vitro* bench testing conducted on the Hi-Torque Command Guide Wire met all acceptance criteria and performed similarly to the predicate devices. There were no new safety or effectiveness issues raised during the testing program.

The Hi-Torque Command Guide Wire Family is substantially equivalent to the predicate devices in regards to the indications for use, materials, fundamental technology, design, performance, shelf life, biocompatibility, sterilization, and packaging and is safe and effective for clinical use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Abbott Vascular, Inc.
c/o Ms. Kay Setzer
Sr. Regulatory Affairs Specialist
P.O. Box 9018
Temecula, CA 92589

NOV 20 2012

Re: K122573
Trade/Device Name: Hi-Torque Command Guide Wire Family
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: August 22, 2012
Received: August 23, 2012

Dear Ms. Setzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

Digitally signed by Matthew G. Hillebrenner
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300213272, cn=Matthew G. Hillebrenner
Date: 2012.11.20 15:52:02 -05'00'

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K122573

Device Name: **Hi-Torque Command** Guide Wire Family

Indications for Use: This Hi-Torque Guide Wire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal angioplasty (PTA), in arteries such as the femoral, popliteal and infra-popliteal arteries. This guide wire may also be used with compatible stent devices during therapeutic procedures.

The guide wire may also be used to reach and cross a target lesion, provide a pathway within a vessel structure, facilitate the substitution of one diagnostic or interventional device for another, and to distinguish the vasculature.

Prescription Use___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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